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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,011	02/09/2007	Reiko Tanaka	Q92322	1047
23373 7590 08/18/2009 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER POLANSKY, GREGG				
ART UNIT		PAPER NUMBER		
1614				
MAIL DATE		DELIVERY MODE		
08/18/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/562,011

**Applicant(s)**

TANAKA, REIKO

**Examiner**

GREGG POLANSKY

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Status of Claims**

1. Applicant's response, filed 5/04/2009, to the Office Action mailed 11/03/2008007 is acknowledged. Applicant has presented arguments in response to the Office Action.
2. Claims 1 and 2 are pending and presently under consideration.
3. Applicant's arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al. (Cancer Letters, Vol. 172, pages 119-126 [see Applicant's 12/23/2005 IDS]), in view of Fan et al., editors ("Mouse Skin tumor Assay", 1996, Toxicology and Risk Assessment: Principles, Methods, and Applications, pages 124-127).

Tanaka et al. teach the instantly claimed compound and its high anti-tumor promoting activity. See Abstract and compound 1 on page 121. Tanaka et al. teach

compound 1 "is considered to be a naturally occurring triterpenoid with the strongest anti-tumor promoting activity in the *in vivo* assay ever known". See page 124, last paragraph. The *in vivo* assay used by Tanaka et al. is a two-stage mouse skin carcinogenesis assay, as described on page 122. The reference discloses that compound 1 is a "promising candidate for effective and safe chemopreventive agents".

Tanaka et al. do not teach the use of the instantly claimed compound (i.e., Tanaka's compound 1) for the treatment of lung tumorigenesis or its oral administration.

Fan et al. teach mouse skin tumor assays and their use as a screening tool for carcinogens and carcinogen promoters. Fan et al. teach a correlation between the mouse skin tumor assay and the mouse lung adenoma assay. Additionally, the reference teaches the use of the skin tumor assays for pharmacological research on chemotherapeutic agents. See pages 124-127, especially the 3<sup>rd</sup> and 4<sup>th</sup> paragraphs on page 127.

It would have been obvious to one of ordinary skill in the art at the time of the invention combine the teachings of Tanaka et al. and Fan et al. The strong anti-tumor promoting activity of the instantly claimed compound, as taught by Tanaka et al., would have motivated the skilled artisan to test the effectiveness of the compound in inhibiting tumorigenesis in other tissues, including the lung. The teaching by Fan et al. of a correlation between the mouse skin tumor and lung adenoma assays would have further motivated the artisan to test the compound for effectiveness in inhibiting lung tumorigenesis.

Oral bioavailability of the instantly claimed compound is a characteristic of the compound. If the compound was bioavailable after oral administration, one of ordinary skill in the art would have been motivated to administer the compound by this route for patient convenience and administration compliance.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Response to Arguments***

6. Applicant argues the Fan et al. reference "may suggest a correlation [between the mouse skin tumor assay and the mouse lung adenoma assay] regarding 'the lowest dose administered systemically that elicits a positive carcinogenic response', [Fan et al.] fails to suggest the correlation on anti-tumor promoting activity between the mouse skin tumor assay and the mouse lung adenoma assay."

Applicant's arguments have been fully considered but they are not persuasive. As discussed above, the strong anti-tumor promoting activity of the instantly claimed compound, as taught by Tanaka et al., would have motivated the skilled artisan to test the effectiveness of the compound in inhibiting tumorigenesis in other tissues, including the lung (a very prevalent form of cancer). The teaching by Fan et al. of a correlation between the mouse skin tumor and lung adenoma assays was cited for providing *further* motivation for one of ordinary skill to test the compound for effectiveness in inhibiting lung tumorigenesis. Fan et al. provide a correlation of carcinogenic activity between the mouse skin tumor assay and the mouse lung adenoma assay (e.g., similar lowest systemic dose having a positive carcinogenic response in both assays).

### ***Conclusion***

7. Claims 1 and 2 are rejected.
8. No claims are allowed.
9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGG POLANSKY whose telephone number is (571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/  
Examiner, Art Unit 1614

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614

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